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S/N 09/841,188

PATENT IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Warmington Examiner: Khatol Shahnan-Shah

Serial No: 09/841,188 Group Art Unit: 1645

Filed: April 25, 2001 Docket No.:

Title: DETECTION OF CANDIDA

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to:

Assistant Commissioner for patents, Washington, D.C. 20231 on _____

By: _____

Name: _____

AFFIDAVIT OF PROFESSOR JOHN WARMINGTON

BOX AF

Assistant Commissioner for Patents
Washington D.C. 20231

Dear Sir:

I, John Warmington, of Rockeby Biomed Limited, declare and state that:

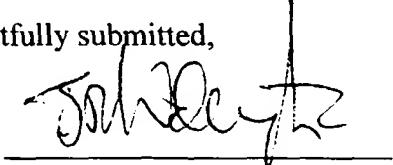
1. I am the applicant/inventor of the invention covered by United States Patent Application Serial No. 09/841,188.
2. Prior to making this declaration I read and considered the Examiners Office Action issued on 6th July 2003.
3. I also reviewed and am familiar with US Pat. No. 4,806,465 in the name of Buckley *et al.*
4. I believe that those skilled in the art would appreciate that the antigens disclosed in United States Patent Application Serial No. 09/841,188 are not the same as those disclosed US Pat. No. 4,806,465 because the molecular weights of the antigens are different. For example, the antigens disclosed in US Pat. No. 4,806,465 have molecular weights of 120 to 135 Kd, 48 to 52 Kd and 35 to 38 Kd. In contrast, the molecular weights of the claimed antigens are 55 kDa, 30 kDa and 20 kDa.
5. I have been aware of the work by Buckley *et al.* for a number of years and was well aware of the antigens and monoclonal antibodies disclosed in US Pat. No. 4,806,465. Indeed, as part of my investigations, I conducted studies on the

antigens disclosed in United States Patent Application Serial No. 09/841,188 using the antibodies disclosed in US Pat. No. 4,806,465. In particular, I obtained samples of the hybridoma cell lines ATCC #HB-8397 and ATCC #HB-8398, which produce monoclonal antibodies that are monospecific to the cytoplasmic antigens disclosed in US Pat. No. 4,806,465 (see abstract of US Pat. No. 4,806,465). I then tested these monoclonal antibodies against samples of the antigens disclosed in United States Patent Application Serial No. 09/841,188. Briefly, these monoclonal antibodies did not react with any of the antigens disclosed in United States Patent Application Serial No. 09/841,188. These data are shown in Figure 1 below. Consequently, I believe that the antigens disclosed and claimed in United States Patent Application Serial No. 09/841,188 are not those disclosed in of US Pat. No. 4,806,465.

6. I declare that all statements made herein on my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful, false statements may jeopardise the validity of the application or patent issuing therefrom.

Respectfully submitted,

By:



Date: 26/9/03

Name: John Warmington

Title: Director of Research & Development, Rockeby Biomed Limited

Figure 1

A). Enolase

Neat γ_{10} γ_{100} γ_{1000}

B). Triple Ag

Neat γ_{10} γ_{100} γ_{1000}

Immunoblot of A). *C. albicans* cytoplasmic (enolase) antigen disclosed in US Pat. No. 4,806,465 and B) the *C. albicans* antigen as disclosed in United States Patent Application Serial No. 09/841,188. The immunoblot was reacted with the monoclonal antibodies that are monospecific to the cytoplasmic antigens disclosed in US Pat. No. 4,806,465.

The monoclonal antibodies reacted with the cytoplasmic antigen (enolase) Figure 1 A, but not with the *C. albicans* antigen as disclosed in United States Patent Application Serial No. 09/841,188 Figure 1 B.